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VIA FEDERAL EXPRESS

July 12, 2013

Ms. Susan E. Liner
Recall Coordinator
U. S. Food and Drug Administration
One Montvale Avenue
Stoneham, MA 02180

Re: Ameridose recall; Recall Numbers: D-054-2013 and D-055-2013 – Status Report and Request for Termination

Dear Ms. Liner:

Pursuant to your request dated December 17, 2012 and as required by Title 21 CFR Part 7 Subpart C Section 7.53, Ameridose is providing the following status report on recalls D-054-2013 and D-055-2013. The information relating to both recalls is combined below. Because of the size of the attachments referenced below, they are being provided to you electronically on the accompanying thumb drive.

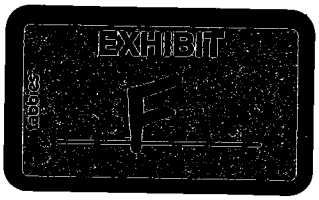
1) Number of consignees notified of the recall, and date and method of notification.

   - 2,615 unique customers (consignees) were notified of the aforementioned recall via email on October 31, 2012, via fax on November 1, 2012, and via US Mail on November 5, 2012. Refer to Attachment 1 for list of customers.

   - Each customer was also contacted by telephone beginning on November 1, 2012. Refer to Attachment 2 (1-5) for documentation of telephone communications.

2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.

   - As of June 17, 2013, Ameridose has received a response from all 2,615 customers acknowledging the recall notification was received by their facility.



- 2,614 customers out of 2,615 have returned recall response forms to Ameridose. This is a response rate of 99.96%.

- For the 2,614 customers who have provided a recall response form as of June 17, 2013, there are 549,430 units in total that were designated on-hand by those customers. Additionally, a total of 36,737 units were designated as discarded/wasted directly by those customers (for a total of 586,167 recall units).

- Refer to Attachment 3 (1-6) for above information.

3) Number of consignees that did not respond.

- All 2,615 customers have responded to Ameridose acknowledging the recall notification was received by their facility.

- There is one customer, University Specialty Hospital, who has not provided a recall response form to Ameridose after repeated attempts to obtain the required information. It appears that the facility is closed.

4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.

- The list and total quantity of products each customer has returned is provided in Attachment 4.

- As of June 21, 2013, 565,650 units have been returned to Ameridose in response to the recall. This quantity and date received for returned units is also documented in Attachment 4. This is a return rate of 103% based on a total of 549,430 total units on hand with customers. Customers returned more medications than they originally indicated was on hand or they returned medications that were outside of the scope of the recall, i.e. medications that were already expired prior to the date of the recall.

- There are two customers who have refused to return some or all of the recalled medications they indicated that they had on hand.
  - Durham Regional Hospital of North Carolina has provided a written statement indicating that they will not return the Ameridose medications that they have on hand in their facility.
  - Kern Medical Center of California has returned a portion of the Ameridose medications that they indicated they had on hand. However, 224 units have not been received. Ameridose has made repeated attempts to obtain the remaining units. However, this facility has indicated that they do not have the resources or time to

return the remaining units and will do so as time permits.

5) Number and results of effectiveness checks that were made.

- As part of Ameridose' s recall strategy, Attachment 5, Ameridose contacted via phone each hospital that did not return the recall response form within a reasonable time after November 1, 2012. This follow up was continued until the response was received. All follow up contact is documented in Attachment 2 (1-5).

6) Estimated time frames for completion of recall.

- June 21, 2013. See below.

Request for Termination of Recalls

Pursuant to 21 CFR Part 7 Subpart C Section 7.55(b), Ameridose is requesting the termination of recalls D-054-2013 and D-055-2013 based on the following information:

- Ameridose has successfully contacted and confirmed recall notification for all 2,615 impacted customers regarding the recall notification as documented in Attachment 2 (1-5).

- Ameridose has received recall responses from 2,614 customers. The only remaining facility that did not return the recall response form appears to have closed.

- Ameridose has received completed recall returns for 2,612 customers out of 2,615. This is a return rate of 99.9%. Additionally, the 2,612 customer have returned 565,650 units out of 549,430 units. As described in the status report above, this is a return rate of 103%.

- The customers who have not provided the required information or medications after numerous contacts by Ameridose are as follows:
  - University Specialty Hospital has not provided a recall response form or recalled medications due to facility closure.
  - Durham Regional Hospital of North Carolina has indicated in writing that they will not provide any of the recalled medications that they indicated they had on hand.
  - Kern Medical Center of California has not provided all of the recalled medications that they indicated they had on hand.

Based on the information provided above, Ameridose believes that it has effectively notified all impacted customers and have secured returns from all but the aforementioned three facilities. Those three facilities have provided documented responses as to the circumstances surrounding their return of recalled medications. Therefore, Ameridose believes that it has fulfilled the recall requirements outlined in 21 CFR Part 7 Subpart C and requests termination of recalls D-054-2013 and D-055-2013.

If you have any questions or concerns about any of the information above or on the enclosed attachments, please do not hesitate to contact me.

Sincerely,

Ingrid S. Martin
Attorney for Ameridose